

FREQUENTLY ASKED QUESTIONS ABOUT New requirements and obligations concerning registration data

Department of Pesticide Regulation

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Recent legislation (Assembly Bill 1011, Chapter 612, Statutes of 2005) changed California law on how the Department of Pesticide Regulation (DPR) treats data submitted in support of product registration.

Previously, DPR was prohibited from considering data submitted by one company to support another company's application to register or amend a pesticide product, without a letter of authorization from the data owner. The new law allows DPR to consider all data it has on file, regardless of the source of the data.

The new law did not change any of DPR's requirements for data, and applicants may still submit their own data in support of a registration application. However, if an applicant does not do so, and expects DPR to rely on another company's data to support its registration application, the applicant may be required to offer to pay the data owner a share of the cost of producing the data.

This obligation relates to two categories of data, and then only if submitted to DPR after January 1, 1991. The first category is data relied on to meet current DPR requirements for registration. The second is data that, although not currently required by DPR, was previously required to obtain, amend, or maintain the registration of a product similar to that of the applicant. The new law sets forth when the obligation to pay for data arises, how the obligation must be met, and what the consequences are for a failure to meet it.



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When will the new law go into effect?

The law is effective January 1, 2006. Any application submitted to DPR on or after that date will be subject to the new law. In addition, previously submitted applications to register new or amend currently registered products that DPR has not acted on by January 1, 2006, will be subject to the new provisions.

Do applicants have to show they have complied with the cost-sharing requirements before their products will be registered?

No. The law does not require DPR to monitor or police data ownership when making registration decisions. The law specifically states that, when making

registration decisions, DPR can rely on evaluations of any data on file, regardless of data ownership. However, if the applicant or the source of the applicant's product is required to make an offer to pay a data owner, this offer must be made by the date an application is submitted to DPR.

What happens if the applicant does not make an offer to pay as required under the law?

If the applicant did not make a required offer to pay, DPR will cancel the registration of the applicant's product. However, DPR has no obligation to verify compliance during the registration process or at any time. The data owner is responsible for notifying the applicant and DPR that an applicant did not make the required offer to pay. If the applicant fails to promptly make an offer to pay or contests the obligation, the data owner and the applicant have 30 days to submit written evidence to DPR supporting their respective positions. DPR, in turn, has 60 days to issue a written finding. If DPR agrees with the data owner, the registration will be cancelled.

Is there any limit on the time the data owner has to notify an applicant of its claim?

Yes. The data owner must notify the applicant of its claim within one year after DPR registers the applicant's product. After a year, the data owner loses its right to make a claim.

What can the data owner or applicant do if it disagrees with DPR's determination regarding an offer to pay?

Either party can appeal the determination to the Superior Court. However, to reverse a determination, the appealing party must show that DPR abused its discretion in making the determination.

Without seeking a determination from DPR, is there any way a data owner can force cancellation of the applicant's product for failure to make an offer to pay?

The data owner can choose to bring an action directly in court.

Does DPR's renewal of a product registered before the law's effective date result in an obligation to make an offer to pay?

No, unless a court declares the original registration to have been unlawfully issued.

Does an applicant have to offer to pay for all data submitted by a data owner for a product?

No. It depends on why the owner's data is on file with DPR. An offer to pay is not required unless DPR required the data to obtain, amend, or maintain the data

Whether an applicant has to offer to pay for data depends on why the data is on file with DPR, and when it was submitted.

owner's product registration. Further, with data that met a previous DPR data requirement, the data owner must be able to show that its data was submitted in response to a specific, documented DPR requirement to obtain, amend or maintain registration of a product substantially similar to the applicant's product.

When does an applicant need to make an offer to pay a data owner?

By the date the application is submitted to DPR. If the applicant has not made an offer because information necessary to identify the obligation and the data owner was not readily available, the applicant must promptly make the offer to pay on receiving the data owner's claim. If the applicant does not make an offer to pay at this time and the data owner proves to DPR that the obligation exists by following the process outlined by the statute, DPR will cancel the registration of the applicant's product.

Does the applicant always have to make an offer to pay for data previously submitted to meet a data requirement of a similar product?

No. The applicant does not need to offer to pay (1) if the applicant submits its own data to satisfy the requirement; (2) has written permission from a data owner to rely on its data; or (3) gets its product from a source that has satisfied the obligations of the statute regarding data. That is, the source has submitted its own data, has written permission from the data owner, or made an offer to pay.

Are there other situations that release the applicant from an obligation to offer to pay for data?

Yes. Periods of data protection vary, depending on when data was submitted to DPR and why it was submitted. Also, there may be no obligation to offer to pay if the data owner and applicant reached an agreement concerning data when the applicant applied for federal registration.

How long is data protected?

- There is no obligation to make an offer to pay for data submitted to DPR **before** January 1, 1991.
- If data was submitted to DPR after January 1, 1991, and before August 2, 2005, **and** it was in support of the first registration of a product, it is protected for 17 years from the date it was submitted to the U.S. Environmental Protection Agency (U.S. EPA), not DPR.
- Data submitted to DPR **after** August 1, 2005 is protected for 15 years.
- Data that was not submitted to support the first registration of a product is protected for 15 years.

The reason for different periods of protection is that DPR generally did not accept applications for registration of new products until after they were

There is no obligation to offer to pay for data submitted to DPR before January 1, 1991.

registered with U.S. EPA. (This has since changed, and DPR is now accepting concurrent applications for registration of new products containing a new active ingredient.)

Giving longer protection to data first submitted to U.S. EPA recognizes that, until recently, most data owners had to wait up to two years between their application to U.S. EPA and subsequent federal registration before they could submit an application and accompanying data to DPR.

What if there is more than one data owner with the necessary data on file?

An offer to pay need be made to only one data owner.

What if there was an arbitration award or cost-sharing agreement at the federal level?

Regardless of when data was submitted to U.S. EPA or DPR, there is no obligation to pay if there was an arbitration award or data cost-sharing agreement on that data between the data owner and the applicant or the applicant's source (under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. sec. 136a), and the use of the data in California was not excluded by the award or agreement's terms.

What if the data owner and the applicant cannot agree on cost-sharing after the irrevocable offer to pay is made?

If the applicant and the data owner cannot agree on the amount and terms of cost-sharing within 90 days of the offer, either party may initiate a proceeding under FIFRA, pursuant to regulations to be adopted by DPR to resolve disputes concerning cost-sharing.


Will DPR's registration decisions be delayed by the time it takes to resolve data cost-sharing?

No. However, if either the applicant or the data owner refuses to take part in the proceeding to resolve cost-sharing, there are significant consequences. If the applicant refuses to participate, fails to comply with an agreement concerning cost-sharing, or to pay the award resulting from the proceeding, DPR must cancel its product. If the data owner refuses to take part in the proceeding or fails to comply with the terms of an agreement, the data owner loses its right to obtain compensation under the statute.

Does the law provide guidance on how to determine how costs shall be shared?

Yes. Under the law, DPR will adopt regulations that require decision makers to consider that the data owner recovered all or part of its costs of generating data by having an exclusive right to sell the pesticide for some period of time.

Time to
resolve data
cost-sharing
will not delay
DPR's
registration
decision.



DPR does not monitor or police data cost-sharing agreements.

Who pays the cost of the proceeding?

The applicant and the data owner share costs equally.

Does DPR monitor compliance with agreements or awards related to data cost-sharing?

No. As with the obligation to make an offer to pay, DPR is not required to verify compliance with agreements or awards related to data cost-sharing. The party who claims noncompliance must notify DPR and the alleged noncomplying party. The procedure in the law used to address an alleged failure to make an offer to pay applies. Each side has 30 days from notification to submit its evidence and arguments to DPR. DPR in turn has 60 days determine if the applicant's product will be cancelled or the data owner's rights forfeited. The decision may be appealed to Superior Court.

Does the law provide more detail on the process to seek a determination from DPR, or on resolving disputes on how costs shall be shared?

No. However, DPR plans regulations to spell this out in more detail.

How will applicants be able to find out what data DPR has on file?

The law requires DPR to make available an index of data submitted in support of registration applications, the ownership of the data, and the date it was submitted to California. DPR recently placed much of this information on its Web site in a searchable database. Go to www.cdpr.ca.gov, click on "Databases," and then on "Pesticide Data Index Search." Information on studies submitted to DPR before 1994 may not include the date DPR received the study or the data owner. Information not in the database can be requested in writing to: California Department of Pesticide Regulation, Pesticide Registration Branch, Public Records Request, P.O. Box 4015, Sacramento, CA 95812-4015, or by email to publicrecords@cdpr.ca.gov.

How can data owners keep abreast of new products that are registered?

DPR will be posting on its Web site a list of newly registered products. The list, updated weekly, will include the brand name, U.S. EPA registration number, and name and address of registrant. The list feature should be available after January 1, 2006. Go to www.cdpr.ca.gov, click on "A-Z Index," then on "List, newly registered products."